IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P. and RHODES TECHNOLOGIES, Plaintiffs, v. COLLEGIUM PHARMACEUTICAL, INC., Defendant.	)	C.A. No. 15-cv-13783 (FDS)

DEFENDANT COLLEGIUM PHARMACEUTICAL, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6)

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Collegium Pharmaceutical, Inc. ("Collegium") respectfully submits this brief in support of its motion to dismiss Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies's (collectively "Purdue") Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim upon which relief can be granted. Specifically, Collegium requests that the Court dismiss this case because U.S. Patent No. 9,073,933 (the "'933 patent") (attached hereto as Exhibit 1) is invalid based on collateral estoppel.

I. INTRODUCTION

Courts can and should apply collateral estoppel of invalidity when a patent is invalid for the same reasons as related patents that have already been adjudged invalid, as in this case. Like the co-pending and related case between the same parties before this Court, this is another straightforward case for the application of collateral estoppel. As Purdue admits in the Complaint, this case is related to consolidated Civil Action Nos. 15-13624 and 15-13099 ("the consolidated cases") that are currently pending before this Court. (Compl. at 1). Not only do the consolidated cases "involve[] the same parties, same Collegium NDA No. 208090, and same accused product" (*Id.*), but they also involve three patents in the same family as and with identical claims (for the purpose of invalidity) to the '933 patent asserted here. The patents at issue in the consolidated cases were the subject of years of litigation in the Southern District of New York, more than 25 lawsuits, and a three-week bench trial which resulted in a finding that they were invalid as obvious. *Purdue Pharma L.P., et al. v. Teva Pharmaceuticals, USA, Inc.*, 994 F. Supp. 2d 367; 1:11-cv-02037-SHS (D.I. 149) (S.D.N.Y. 2014) (attached to Collegium's concurrently filed Request for Judicial Notice as Exhibit A) ("the New York Action").

In the consolidated cases, Collegium has moved for partial judgment on the pleadings based on the doctrine of collateral estoppel. Specifically, Collegium has requested that the Court enter final judgment of invalidity of those three patents – U.S. Patent Nos. 7,674,799 (the "'799 patent") (Ex. C to Request for Judicial Notice), 7,674,800 (the "'800 patent") (Ex. D to Request for Judicial Notice), and 7,683,072 (the "'072 patent") (Ex. E to Request for Judicial Notice) (collectively "the Invalidated Patents") – because Judge Stein in the Southern District of New York has already found them invalid and entered a final judgment as to invalidity. Purdue explicitly admitted in the pleadings in the consolidated cases that the Invalidated Patents asserted in that case have been finally adjudged invalid in a prior action to which the Purdue plaintiffs were parties. (Civil Action No. 15-13624, Complaint at ¶ 23). Additionally, in its memorandum in opposition to Collegium's motion for judgment on the pleadings, Purdue did not refute Collegium's assertion that the Invalidated Patents are appropriately the subject of collateral estoppel. (Civil Action No. 15-13099, Mem. of Law in Opp. To Def's Mot. for Partial Judgment at 6–7). Instead, Purdue sought delay of a judgment of collateral estoppel.

As discussed in more detail below, the claims of the '933 patent asserted here present no new issues of invalidity—they are substantially *identical* to the claims already invalidated by Judge Stein. This case therefore involves the same issues that Plaintiffs fully and fairly litigated in the New York Action. Accordingly, for the reasons stated below, Collegium respectfully requests that the Court grant Collegium's Rule 12(b)(6) motion to dismiss for failure to state a claim based on collateral estoppel.

II. BACKGROUND

A. The Patents-in-Suit

The Invalidated Patents were invalidated on identical grounds because they are all in a single family and raise substantially identical issues of invalidity. The '933 patent asserted in this

case is simply a fourth member in that same family, and likewise raises the same issues of invalidity. The Invalidated Patents and the '933 patent are all entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE." The Invalidated Patents and the '933 patent are part of the same patent family and have identical specifications. The Invalidated Patents are continuations of application No. 11/391,897, and the '933 patent is a continuation of the application that issued as the '072 patent. Each patent recites a formulation of oxycodone (the active pharmaceutical ingredient in Purdue's OxyContin®) with low levels of 14-hydroxycodeinone ("14-hydroxy"), a compound with an α,β-unsaturated ketone ("ABUK") moiety, which is a structural alert for mutagenicity.

The specification describes a process for making oxycodone API (active pharmaceutical ingredient) (specifically oxycodone hydrochloride) that is substantially free of 14-hydroxy. As Figure 1 shows, the process begins with thebaine. First, thebaine is oxidized to form 14-hydroxy. 14-hydroxy is then hydrogenated to form oxycodone free base. Finally, oxycodone free base is exposed to hydrochloric acid which acidifies the oxycodone free base, resulting in oxycodone hydrochloride—the salt formation step. During the first step of the process, some thebaine is over-oxidized, which yields a byproduct known as 8α,14-dihydroxy-7,8-dihydrocodeinone ("8α"). When 8α is exposed to hydrochloric acid during the salt formation step, some of the 8α is converted into 14-hydroxy. Thus, 14-hydroxy reappears during the salt formation step and is removed in a second hydrogenation step.

While the specification describes a process for making oxycodone hydrochloride having minimal 14-hydroxy, the claims at issue of each of the patents are product claims. This means that, at least for purposes of invalidity, the claims are directed to the end product—not the specific method of manufacture. As described below, each of the claims of the '933 patent claim

end products that are identical to products claimed in claims invalidated by the court in the Southern District of New York.

B. The New York Action

As mentioned above, the three Invalidated Patents were the subject of prior litigations in the Southern District of New York. After a three-week bench trial in the lead case, the court in the Southern District of New York issued a decision invalidating the asserted claims[1] of the three Invalidated Patents (that decision refers to the Invalidated Patents as the Low-ABUK patents) as obvious under 35 U.S.C. § 103. *See* Ex. A. As discussed in Collegium's concurrently filed Request for Judicial Notice, the New York Court's decision is an adjudicative fact, the authenticity of which cannot be disputed, and is therefore appropriately the subject of judicial notice pursuant to Rule 201(b) of the Federal Rules of Evidence.

During claim construction, the New York court found that each of the asserted claims was a product-by-process claim. *Id.* at 48 n.6. Based on this finding, the court was required to assess only the validity of the product limitations of the claims and to disregard the process limitations. *Id.* at 48. The court concluded that each of the asserted claims was invalid because the product claimed was obvious in light of the prior art. *Id.* at 55–57. Specifically, the court found that the prior art taught how to create oxycodone API and taught hydrogenation of an oxycodone salt to remove 14-hydroxy. Thus it would have been obvious to a skilled artisan to hydrogenate the oxycodone hydrochloride to reduce the level of 14-hydroxy in the end product. *Id*.

Based on its decision in the *Teva* case, the Southern District of New York entered judgment of invalidity based on collateral estoppel in other cases involving the Invalidated

[1] The following claims were asserted and invalidated in the New York Action: Claims 3 and 19 of the '799 patent; Claims 30-34 and 76-79 of the '800 patent; and Claims 1, 4, and 5 of the '072 patent.

Patents. *See e.g. Purdue Pharma L.P., et al. v. Amneal Pharmaceuticals, LLC*, 11-cv-8153-SHS, D.I. 86 (S.D.N.Y. Jan. 29, 2014) (Ex. B to Request for Judicial Notice). Collegium has also requested that the Court take judicial notice of this order, which constitutes an adjudicative fact. In the *Amneal* proceeding, Purdue "agreed that collateral estoppel based on the *Teva* decision precludes Plaintiffs' claims for relief" in the other cases. *Id*. at 2. As such, in other cases, Purdue has admitted that collateral estoppel precludes its claim for relief for alleged infringement of the Invalidated Patents. Similarly, in the consolidated cases, Purdue has not refuted Collegium's assertion that the Invalidated Patents are subject to collateral estoppel. (Civil Action No. 15-13099, Mem. of Law in Opp. To Collegium's Mot. for Partial Judgment at 6–7 ("If the *Teva* judgment is ultimately affirmed, that will, as Collegium notes, eliminate the need for further litigation regarding the [Invalidated] Patents.")). As discussed in greater detail below, for purposes of invalidity, the claims of the '933 patent are identical to the claims of the Invalidated Patents that were invalidated by the court in the Southern District of New York.

III. ARGUMENT

A. Legal Standards

The affirmative defense of collateral estoppel may be raised in a motion under Rule 12(b)(6). "As a general rule, a properly raised affirmative defense can be adjudicated on a motion to dismiss so long as (i) the facts establishing the defense are definitively ascertainable from the complaint and the other allowable sources of information, and (ii) those facts suffice to establish the affirmative defense with certitude." *Yong Li v. Huffman*, No. 11-11557-NMG, 2012 U.S. Dist. LEXIS 91695, *13 (D. Mass. May 18, 2012) (citing *Rodi v. S. New Eng. Sch. of Law*, 389 F.3d 5, 12 (1st Cir. 2004)). While a court must accept all well-pleaded facts set forth in the complaint as true and draw all inferences in favor of the pleader, a court may also "augment these facts and inferences with data points gleaned from documents incorporated into the

complaint, matters of public record, and facts susceptible to judicial notice." *Id.* at *13 (quoting *Haley v. City of Boston*, 657 F.3d 39, 46 (1st Cir. 2011)). Pursuant to Rule 201(b)(2) of the Federal Rules of Evidence, this Court may "judicially notice a fact that is not subject to reasonable dispute because it: can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Orders issued by other courts are appropriately the subject of judicial notice. *See Defeudis v. Defeudis,* 2011 U.S. Dist. LEXIS 3927, *11 n.5 (D. Mass. Jan. 13, 2011) (noting that a court may take judicial notice of an order of another judge) (quoting *Rodi v. S. New Engl. Sch. of Law*, 389 F.3d 5, 19 (1st Cir.2004) ("It is well-accepted that federal courts may take judicial notice of proceedings in other courts if those proceedings have relevance to the matters at hand.")). A court may also take judicial notice of patents and patent file histories because they are matters of public record. *Esoterix Genetic Labs. LLC v. Qiagen Inc*., 2015 U.S. Dist. LEXIS 129310, *2 n.1 (D. Mass. Sept. 25, 2015) (*citing Hoganas AB v. Dresser Indus., Inc*., 9 F.3d 948, 954 n.27 (Fed. Cir. 1993)); *Standard Havens Prods. v. Gencor Indus*., 897 F.2d 511, 514 (Fed. Cir. 1990).

"Issue preclusion (also called collateral estoppel) 'prevents a party from relitigating issues that have been previously adjudicated.'" *Manganella v. Evanston Inc. Co*., 700 F.3d 585, 591 (1st Cir. 2012) (citation omitted). Generally, the law of the regional circuit applies to collateral estoppel determinations. *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citing *Aspex Eyewear, Inc. v. Zenni Optical Inc.,* 713 F.3d 1377, 1380 (Fed. Cir. 2013)). In the First Circuit, collateral estoppel applies where "(1) the issues raised in the two actions are the same; (2) the issue was actually litigated in the earlier action; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was necessary to that judgment." *Manganella*, 700 F.3d at 591. Where aspects of this determination

involve substantive issues of patent law, such as "whether a particular [patent] claim . . . is the same as or separate from another claim," Federal Circuit law applies. *Ohio Willow Wood*, 735 F.3d at 1342.

"[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel." *Mendenhall v. Barber-Green Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971)). "If an alleged infringer raises the defense of collateral estoppel, the burden is on the patentee 'to demonstrate, if he can, that he did not have a fair opportunity procedurally, substantively and evidentially to pursue his claim the first time.'" *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1376 (Fed. Cir. 1983) (citation omitted). The Court's "inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits." *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999).

Collateral estoppel applies even to patent claims that have not been previously adjudicated. Federal Circuit "precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply." *Ohio Willow Wood*, 735 F.3d at 1342 (citing *Bourns, Inc. v. U.S.*, 537 F.2d 486, 491, 210 Ct. Cl. 642 (Ct. Cl. 1976); *Westwood Chem., Inc. v. U.S.*, 525 F.2d 1367, 1372, 207 Ct. Cl. 791 (Ct. Cl. 1975)) (emphasis in original). "If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.* (citing *Bourns*, 537 F.2d at 491). Courts compare the language of the adjudicated claims with the language of the related, unadjudicated claims to

determine whether the differences materially alter the invalidity determination. If the differences between the claim language are not "patentably significant," courts may apply collateral estoppel to invalidate the previously unadjudicated claims. *See Id.* at 1342–43 (affirming district court's invalidation of previously unadjudicated claims based on collateral estoppel because the claims used "slightly different language to describe substantially the same limitation"); *Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1319 (Fed. Cir. 2015) (comparing the unadjudicated claim with the related adjudicated claim and holding the unadjudicated claim invalid based on collateral estoppel because the claim's additional limitation did not change the invalidity analysis).

Finally, "[a] product-by-process claim is 'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 (1989)). For a product-by-process claim, the invalidity analysis focuses on the validity of the product, and courts must disregard any process limitations. The Federal Circuit has held that "it is clear that [product-by-process] claims are always to the product, not a process." *Id.* at 1317. Thus, "if the product in a product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable . . . ." *Id.* The validity analysis for a product-by-process claim therefore differs from the infringement analysis – infringement requires that the claimed product is made by the claimed process. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc).

B. Collegium is Entitled to Dismissal under Rule 12(b)(6) Based on Collateral Estoppel From the New York Action.

This is a straightforward case for the application of collateral estoppel. Purdue has admitted in the pleadings in the consolidated cases that the Invalidated Patents were invalidated

in a final judgment in the New York Action. For purposes of invalidity, as described below, the claims of the '933 patent are materially the same as the claims invalidated by the Southern District of New York. The New York court's Findings of Fact and Conclusions of Law are adjudicative facts that may be judicially noticed and are therefore appropriate for the Court to consider in deciding this motion to dismiss under Rule 12(b)(6). Fed. R. Evid. 201(b); s*ee Defeudis v. Defeudis,* 2011 U.S. Dist. LEXIS 3927, *11 n.5 (D. Mass. Jan. 13, 2011) (noting that a court may take judicial notice of an order of another judge) (quoting *Rodi v. S. New Engl. Sch. of Law*, 389 F.3d 5, 19 (1st Cir.2004)).

1. The claims of the '933 patent present the same issues of invalidity as the Invalidated Patents.

The invalidity issues raised in this action and in the New York Action are the same. Although Purdue now asserts a different patent than those invalidated in the New York Action, the differences between the adjudicated claims of the Invalidated Patents and the claims of the '933 patent do not present new issues of invalidity. The '933 patent is simply a fourth member of the family of three that have already been invalidated.

As an initial matter, during prosecution of the '933 patent, all of the claims were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-14 of the '072 patent, claims 1-9 of the '799 patent and claims 38-55 of the '800 patent. '933 Patent File History, 7/1/14 Office Action at 5-6 (Ex. F to Request for Judicial Notice)). In issuing that rejection, the Examiner stated that "[a]lthough the conflicting claims are not identical, they are *not patentably distinct* from each other because Oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone of the ['072 patent] encompasses instant claims." *Id*. (emphasis added). Rather than making any argument as to why the claims of the application that became the '933 patent were patentably distinct from the claims

of the Invalidated Patents, Purdue merely submitted terminal disclaimers[2] to dispose of the double patenting rejection. *Id.*, 10/1/14 Response to Office Action at 13.

"The judicially-created doctrine of obviousness-type double patenting cements [the] legislative limitation [of § 101] by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentabily distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). "[A] terminal disclaimer may restrict the slight variation to the term of the original patent and cure the double patenting rejection." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 (Fed. Cir. 2003). Stated another way, the filing of a terminal disclaimer is a way to allow claims that are not patentably distinct from claims in an earlier patent by limiting the term of the later claims to the term of the earlier claims. Accordingly, the Examiner's determination that all claims of the '933 patent were not patentably distinct from Purdue's earlier patents, including the invalidated claims of the Invalidated Patents is evidence that collateral estoppel of invalidity is appropriate. A more fulsome comparison of the claims of the '933 patent and the '072 patent follows.

The '933 patent has three independent claims – Claims 1, 10, and 16. Claims 1 and 16 are both product claims, which are directed to oxycodone hydrochloride with less than 25 ppm 14-hydroxy. Claim 10 is a product-by-process claim directed to the same product.

Claim 1 of the '933 patent claims the same product as Claim 1 of the '072 patent, which stands invalid. Ex. A at 56.

[2] In filing the terminal disclaimers, Plaintiffs' prosecution counsel made the typical attorney statement that no admission as to obviousness type-double patenting was intended, but provided no argument or evidence to dispute the determination of the Examiner that the claims were not patentably distinct from the earlier application and patents. Defendants offer the expert determination of the Examiner as persuasive evidence that the claims are not patentably distinct from the earlier application and patents identified by the Examiner.

’933 Patent, Claim 1	’072 Patent, Claim 1
An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.	An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.

Because Claim 1 of the ’072 patent is a product-by-process claim, the invalidity issue previously litigated was the validity of the ultimately claimed product. *Id*. at 48. The New York Court concluded that the product of Claim 1 of the ’072 patent is “oxycodone API having less than 25 ppm [14-hydroxycodeinone].” *Id.* at 56. The court held that the process limitation that “at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone” added “no patentable significance for the purposes of validity.” *Id.* Thus, the collateral estoppel analysis depends strictly on a product-to-product comparison between Claim 1 of the ’933 patent and Claim 1 of the ’072 patent.

Both Claim 1 of the ’933 patent and Claim 1 of the ’072 patent claim an oxycodone hydrochloride composition with less than 25 ppm 14-hydroxy.[3] While Claim 1 of the ’933 patent additionally claims the presence of 8α,14-dihydroxy-7,8-dihydrocodeinone (“8α”), the inclusion of that limitation does not distinguish it from Claim 1 of the ’072 patent. First, Claim 1 of the ’072 patent explicitly contemplates that 14-hydroxy is derived from 8α. That conversion does not fully eliminate 8α, and therefore some 8α necessarily remains in the final product. Similarly, as explained in the patent specification, 8α is necessarily present as a byproduct in the product claimed by Claim 1 of the ’072 patent. For example, the specification states that

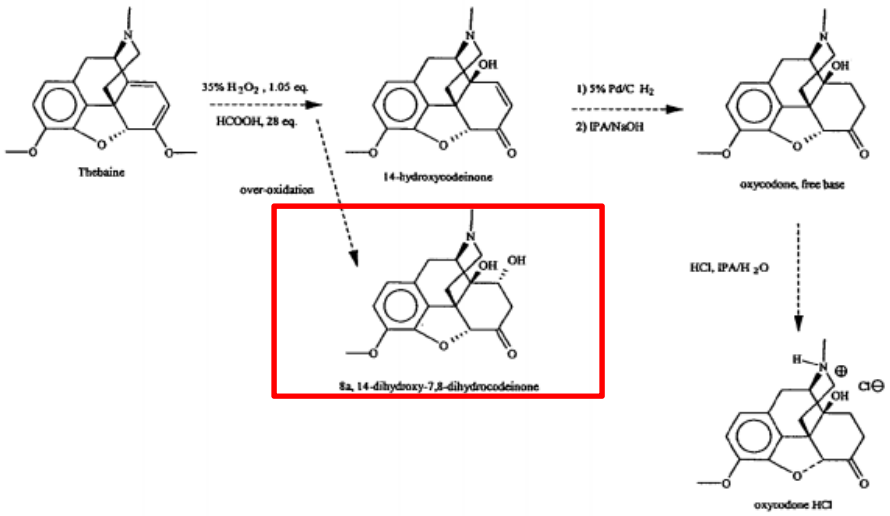
> [d]uring the oxidation of thebaine to give 14-hydroxycodeinone, several overoxidized products are formed including 8,14-dihydroxy-7,8-

[3] The specification defines active pharmaceutical ingredient -“API” - as a type of “composition.” *See, e.g.,* Ex. C, ’072 at col. 6 ll. 31–32.

> dihydrocodeinone.[4] *In the production of oxycodone free base from the 14-hydroxycodeinone, the 8,14-dihydroxy-7,8-dihydrocodeinone is carried through the process*. During conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into 14-hydroxycodeinone.

Ex. C, '072 patent at col. 1, l. 64–col. 2, l. 5 (footnote added) (emphasis added). The specification further states that "[i]n certain embodiments, the invention is directed to the conversion of an oxycodone free base composition (with an 8,14-dihydroxy-7,8-dihydrocodeinone component) to oxycodone hydrochloride." *Id.* at col. 8, ll. 4–7. Also, Figure 1 of the '072 patent shows that the process used to synthesize oxycodone hydrochloride from thebaine results in the production of 8α:

FIGURE 1



Reaction scheme of the process used to produce oxycodone HCl from thebaine.

[4] The specification defines 8,14-dihydroxy-7,8-dihydrocodeinone as including 8α. *See* Ex. C, '072 patent at col 5, ll. 54–57.

Claim 1 of the ’933 patent does not identify a specific amount of 8α that must be present. The limitation can therefore be satisfied merely by the presence of trace amounts, which is consistent with the fact that 8α is never completely eliminated and is carried through the process. Thus, Claim 1 of the ’933 patent does not claim a different product than Claim 1 of the ’072 patent. It merely identifies a byproduct that is necessarily present in the product due to the process used to synthesize oxycodone hydrochloride. *See Alcon Research, LTD. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (explaining that an inherent property is one that is necessarily present in the claimed invention). The Federal Circuit has held that the identification of an inherent property cannot make an obvious claim nonobvious. “To hold otherwise would allow any formulation – no matter how obvious – to become patentable merely by testing and claiming an inherent property.” *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012). Therefore, because the identification of 8α adds “nothing of patentable consequence,” Claim 1 of the ’933 patent is invalid as obvious based on collateral estoppel. *In re Kao,* 639 F.3d 1057, 1070 (Fed. Cir. 2011).

Similarly, the disclosure of “[a]n oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride” is inherent in the Claims of the ’072 patent. In fact, the ’072 patent states that “[p]referably, the oxycodone hydrochloride preparation is oxycodone hydrochloride API and contains at least 95% oxycodone hydrochloride, at least 98% oxycodone hydrochloride, at least 99% oxycodone hydrochloride, or at least 99.9% oxycodone hydrochloride.” Ex. E, ’072 patent at col. 5 l. 65 – col. 6 l. 3). Accordingly, the disclosure of a composition comprising at least 95% oxycodone hydrochloride is inherent in the claims of the ’072 patent and adds “nothing of patentable consequence” to the claims of the ’933 patent.

Claims 1 and 16 of the ’933 patent are identical but for the addition in Claim 16 of the language: “less than 5 ppm of codeinone.”

’933 Patent, Claim 16
An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, less than 5 ppm of codeinone, and less than 25 ppm of 14-hydroxycodeinone.

The collateral estoppel analysis for Claim 16 is substantially the same as the analysis for Claim 1. As discussed above, the 8α and 95% oxycodone hydrochloride limitations do not confer patentability. Further codeinone is another type of ABUK that is necessarily present in the oxycodone hydrochloride composition claimed in the ’072 patent. *See* Ex. E, ’072 patent at col. 6 ll. 46–49 (“The process of the present invention may result in the reduction of other [ABUKs] in oxycodone compositions, in addition to 14-hydroxycodeinone, such as, e.g. codeinone.”). If codeinone was not present in the product claimed by Claim 1 of the ’072 patent, the ’072 specification would not disclose how to test its concentration. *See id.,* Example 6 at col. 31, 1.20 - col. 34 l.54 (“Analysis of Sample to Determine 14-Hydroxycodeinone and Codeinone.”). Again, simply identifying additional molecules that are inherently present in a product that has been invalidated cannot confer validity. Claim 16 of the ’933 patent is therefore also obvious based on collateral estoppel.

The claims that depend from Claims 1 and 16 merely recite lower levels of 14-hydroxy in the ultimately claimed product. For example, Claim 2 is directed to the same oxycodone hydrochloride composition as Claim 1, but with a purity level of 15 ppm of 14-hydroxy, rather than 25 ppm. As an initial matter, Claim 1 of the ’072 patents disclosure of a composition having “less than 25 ppm 14-hydroxycodeinone” is broad enough that it encompasses the lower purity limitations claimed in the claims that depend from Claims 1 and 16 of the ’933 patent. There is

no lower purity limit disclosed in Claim 1 of the '072 patent, and thus it necessarily covers compositions having purity levels of as low as of 0.25 ppm.

Similarly, the New York court held that dependent claims 4 and 5 of the '072 patent, which also merely recited lower levels of 14-hydroxy, were invalid as obvious because "achieving these purity levels would have been obvious in light of [the prior art]". Ex. A at 56. The court explained that "it would have been obvious to a skilled artisan to meet those purity limits by using hydrogenation and . . . repeat that hydrogenation if necessary to complete the reaction."[5] *Id.* The '072 patent Claims 4 and 5 are reproduced below in comparison to the claims that depend from Claims 1 and 16 of the '933 patent. The remaining claims of the '072 patent were not asserted in the New York Action, but would also be invalid under the New York Court's reasoning that specific purity levels can be reached through additional hydrogenation—and that reaching those purity levels would have been obvious.

'933 Patent	'072 Patent
2. The oxycodone hydrochloride composition of claim 1, having less than 15 ppm of 14-hydroxycodeinone.	4. The oxycodone hydrochloride active pharmaceutical ingredient of claim 1 having less than 15 ppm 14-hydroxycodeinone.
3. The oxycodone hydrochloride composition of claim 1, having less than 10 ppm of 14-hydroxycodeinone.	5. The oxycodone hydrochloride active pharmaceutical ingredient of claim 1 having less than 10 ppm 14-hydroxycodeinone.
4. The oxycodone hydrochloride composition of claim 1, having less than 5 ppm of 14-hydroxycodeinone.	
5. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.25 ppm.	
6. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.5 ppm.	

[5] Even though this explanation corresponds to the invalidated dependent claims of the '800 patent, it applies equally to the invalidated claims of the '072 patent because Claims 34-35 and 78-79 of the '800 patent add the same purity limitations as Claims 4 and 5 of the '072 patent.

7. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 1 ppm.
8. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 2 ppm.
9. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 5 ppm.
17. The oxycodone hydrochloride composition of claim 16, having less than 5 ppm of 14-hydroxycodeinone.
18. The oxycodone hydrochloride composition of claim 16, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.25 ppm.
19. The oxycodone hydrochloride composition of claim 16, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.5 ppm.
20. The oxycodone hydrochloride composition of claim 16, wherein the composition has a lower limit of 14-hydroxycodeinone of 1 ppm.

The "less than 5 ppm", "less than 10 ppm", and "less than 15 ppm" 14-hydroxy limitations are inherent in the product of Claim 1 of the '072 patent, which claims an oxycodone hydrochloride composition with less than 25 ppm 14-hydroxy. "Less than 25 ppm" necessarily encompasses levels of 14-hydroxy that are lower than 25 ppm. The "lower limit" limitations are also inherent. The specification of the '072 patent discloses that "[i]n certain embodiments, the oxycodone hydrochloride composition of the present invention has a lower limit of 0.25 ppm, 0.5 ppm, 1 ppm, 2 ppm or 5 ppm of 14-hydroxycodeinone." Ex. C, '072 patent at col. 3, ll.45-48. Purdue has therefore already litigated, and lost, the issue of whether a purer oxycodone hydrochloride composition is nonobvious. Thus, dependent claims 2-9 and 17-20 are invalid as obvious based on collateral estoppel.

Claim 10 of the ’933 patent is a product-by-process claim because it defines the product – oxycodone hydrochloride with less than 25 ppm 14-hydroxy – in terms of the process by which it is made. *See SmithKline Beecham Corp. v. Apotex Corp.,* 439 F.3d 1312, 1315 (Fed. Cir. 2006); 3-8 Chisum on Patents § 8.05 (2015).

’933 Patent, Claim 10
A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

For purposes of determining invalidity, the Court may only assess the product claimed and must disregard any process limitations. *Id.* at 1317. When the process limitations are disregarded, Claim 10 of the ’933 patent is directed to the same product that is claimed in Claim 1 of the ’072 patent. In the New York Action, the court found oxycodone hydrochloride with less than 25 ppm 14-hydroxy invalid. Purdue should be precluded from relitigating the validity of the same product in this case.

The claims that depend from Claim 10 are all product-by-process claims that merely recite additional specific process limitations for making the same product already determined to be obvious by the court in the Southern District of New York. As discussed above, the additional process limitations cannot confer patentability. As such, the additional process limitations added in the claims that depend from Claim 10 are irrelevant for purposes of validity. The dependent claims are reproduced below in comparison to Claim 1 of the ’072 patent.

’933 Patent	’072 Patent
11. The process of claim 10, comprising combining hydrochloric acid and the oxycodone base composition in a solvent to form a solution, and isolating the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone from the solution.	1. An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.
12. The process of claim 10, wherein the	

oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone is isolated from the solution by lyophilizing or spray drying the solution.
13. The process of claim 12, wherein the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone is isolated from the solution by crystallization and filtration.
14. The process of claim 10, wherein the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone is formed by hydrogenation
15. The process of claim 10 comprising reacting the oxycodone base composition with an acid having a higher pH than hydrochloric acid to form an corresponding acid addition salt of oxycodone, and converting the acid addition salt of oxycodone to oxycodone hydrochloride.

Because these dependent claims are also product-by-process claims, and because the product of all these claims is the same product that was invalidated in the New York Action, claims 11-15 of the ’933 patent are invalid based on collateral estoppel.

Accordingly, as described above, all of the claims of the ’933 patent are patentably indistinct from the claims of the Invalidated Patents which were invalidated by Judge Stein in the Southern District of New York.

2. The remaining collateral estoppel factors are also satisfied.

The issue of validity was actually litigated in the earlier action. In the New York Action, the validity of the Invalidated Patents was tried in a three-week bench trial and Judge Stein of the Southern District of New York issued a 115-page decision setting forth findings of fact and conclusions of law in which he found the Invalidated Patents invalid. Ex. A. Second, the issue of validity was determined by a valid and binding final judgment. As noted above, Judge Stein entered final judgment of invalidity of the Invalidated Patents in the *Teva* case and entered final

judgments of invalidity of the Invalidated Patents on the basis of collateral estoppel in related cases based on its final judgment in the *Teva* case. *E.g.,* Ex. B. Further, in those cases, Purdue admitted that collateral estoppel of invalidity of the Invalidated Patents was appropriate. *Id.* at 2. Finally, the determination of invalidity was necessary to that final judgment—the final judgment was of invalidity.

It cannot be disputed that all four elements necessary to find collateral estoppel are present in this case and numerous courts have found collateral estoppel to apply in analogous cases. *See e.g. Ohio Willow Wood Co. v. Alps South, LLC,* 735 F.3d 1333, 1342–43 (Fed. Cir. 2013) (affirming district court's grant of summary judgment of invalidity of previously unadjudicated claims based on collateral estoppel because they presented the same invalidity issues as patent claims that stood invalid); *Mendenhall v. Barber-Green Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (finding invalidity on the basis of collateral estoppel even where the invalidity judgment was entered after the appeal of the second case); *Zoll Medical Corp. v. Philips Elecs. N.A. Corp.*, Civ. No. 14-10029-NMG, 2014 U.S. Dist. LEXIS 51251, **9-11 (D. Mass. Apr. 11, 2014) (dismissing a case on the basis of collateral estoppel based on a prior judgment of non-infringement by a related product); *Juxtacomm-Texas Software, LLC v. Lanier Parking Sys. of Va., Inc.*, 944 F. Supp. 2d 469 (E.D. Va. 2013) (granting a motion for judgment on the pleadings on the basis of collateral estoppel based on a prior judgment of invalidity for indefiniteness); *Galderma Labs. Inc. v. Amneal Pharmaceuticals, LLC*, 921 F. Supp. 2d 278 (D. Del. 2012) (granting judgment on the pleadings of non-infringement based on collateral estoppel where the first case involved a product with a slightly different formulation than in the second case).

The fact that Purdue has appealed the decision in the New York Action is irrelevant. The pendency of an appeal does not diminish either the finality or binding effect of a trial court's

holding. *See Pharmacia & UpJohn Co.*, 170 F.3d at 1381 (Fed. Cir. 1999); *see also Novo Nordisk, Inc. v. Paddock Labs., Inc.*, 797 F.Supp.2d 926, 934 (D. Minn. 2011) (entering final judgment of invalidity and unenforceability on the basis of collateral estoppel while an appeal of the original decision was pending and refusing to stay the litigation pending the appeal), *rev'd in part on other grounds* 515 Fed. App'x 889 (Fed. Cir. 2013). Accordingly Purdue's appeal of the New York Action decision does not preclude this Court from entering judgment of invalidity on the basis of collateral estoppel now.

IV. CONCLUSION

For the reasons set forth above, Collegium respectfully requests that the Court grant Collegium's Rule 12(b)(6) motion to dismiss for failure to state a claim.

Respectfully submitted,

Date: December 1, 2015

By */s/ Jake M. Holdreith*

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) this1st day of December, 2015.

/s/ Jake M. Holdreith
Jake M. Holdreith (admitted *pro hac vice*)

CERTIFICATE OF CONFERENCE

I hereby certify that counsel for the parties named in this matter have met and conferred and have attempted in good faith to resolve or narrow the issue this 1st day of December, 2015.

/s/ Jake M. Holdreith
Jake M. Holdreith (admitted *pro hac vice*)